

Applicants: Norman Latov and Armin Alaeddini
U.S. Serial No.: 09/825,572
Filed: April 3, 2001
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have hereinabove canceled claims 13, 23, 24, and 25 without prejudice, amended claims 1, 4, 9, 20, and 26, and added new claim 27. Applicants maintain that the amendments to the claims raise no issue of new matter. Support for the amendments to claim 1 can be found in the specification as originally filed at, *inter alia*, page 8, lines 17-27; page 9, lines 3-6; and at page 11, lines 17-18. Support for the amendments to claim 4 can be found in the specification as originally filed at, *inter alia*, page 9, lines 22-23. Support for the amendments to claim 9 can be found in the specification as originally filed at, *inter alia*, page 11, lines 2-3. Support for the amendments to claim 20 can be found in the specification as originally filed at, *inter alia*, page 13, lines 15-19, and lines 24-25. Support for the amendments to claim 26 can be found in the specification as originally filed at, *inter alia*, page 15, lines 4-8. Support for new claim 27 can be found in the specification as originally filed at, *inter alia*, page 2, lines 5-6, 11-20, and 30-33; page 3, lines 31-32; page 5, lines 6-11; at page 14, lines 15-17; and in figure 1. In accordance with M.P.E.P. §809.02(a), applicants note that new claim 27 is readable upon the elected species, namely ganglioside. Accordingly, applicants respectfully request that this Amendment be entered. After entry of this Amendment claims 1, 4, 6, 7, 9-12, 14, 20, 26, and 27 will be pending and under examination.

Rejections Under 35 U.S.C. §112 (second paragraph)

In the December 20, 2002 Office Action, the Examiner stated that claims 1, 4, 6, 7, 9-14, 20, and 23-26 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention. The Examiner stated that claim 1 is vague, and that in line 7 of claim 1 the recitation of "the change" lacks antecedent support, and that claim 9 is vague because it depends from non-elected claim 8. The Examiner also stated that claim 20 is vague as in line 1, the recitation of "the optical signal size" lacks antecedent support. The Examiner further stated that in line 4, the recitation of "the secondary antibody" lacks antecedent support.

In response, without conceding the correctness of the Examiner's position and in order to expedite prosecution, applicants have hereinabove amended claims 1, 4, 9, 20, and 26, added new claim 27, and canceled claims 13, 23, 24, and 25 without prejudice. Applicants maintain the amended claims satisfy the provisions of 35 U.S.C. §112, second paragraph, and request the Examiner to reconsider and withdraw the rejection.

The Examiner stated that claims 23-26 provide for the use of the method of claim 1, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. The Examiner stated that a claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. The Examiner further stated that claims 23-26 are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101.

In response, without conceding the correctness of the Examiner's

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position and in order to expedite prosecution, applicants have hereinabove canceled claims 23, 24, and 25 without prejudice, and amended claim 26. Applicants maintain that claim 26 satisfies the provisions of 35 U.S.C. §101 and does not recite a use without setting forth any steps, and therefore request the Examiner to reconsider and withdraw the rejection.

Rejections Under 35 U.S.C. §102(b)

The Examiner stated that claims 1, 11, 12, and 24 are rejected under 35 U.S.C. §102(b) as being anticipated by Malmqvist et al. The Examiner stated that Malmqvist et al. (U.S. Patent No. 5,492,840) discloses a sensor unit and method of assay that uses surface plasmon resonance, and that the sensor unit comprises a glass plate that has been coated with a thin film of metal, such as silver or gold. The Examiner further stated that the metal film is coated with an organic polymer or hydrogel forming a basal surface which contains functional groups for binding of desired specific binding reagents, such as antibodies or antigens, and that the hydrogel can be carboxymethyl derivatives of dextran (col. 4, lines 5-67).

In response, applicants respectfully traverse the Examiner's rejection.

To anticipate the method of claims 1, 11, 12, and 24, Malmqvist et al. would have to teach each and every element thereof. It does not. Specifically, Malmqvist et al. does not teach a method of detecting antibodies in a blood or blood derivative solution comprising contacting the blood or blood derivative solution with

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a ganglioside-coated surface of a sensor chip.

The Examiner stated that claims 1, 11, 12, and 24 are rejected under 35 U.S.C. §102(b) as being anticipated by Fagerstam et al. The Examiner stated that Fagerstam et al. (*Journal of Chromatography*, 597 (1992), pp 397-410) discloses a system for biospecific interaction analysis in which surface plasmon resonance (SPR) detection is combined with a dextran-modified sensor chip to which one of the components of the interaction under study can be covalently attached (page 398, left column). The Examiner further stated that the sensor chip has a layer of carboxymethylated dextran on its surface for immobilization of antigens or antibodies (page 400).

In response, applicants respectfully traverse the Examiner's rejection.

To anticipate the method of claims 1, 11, 12, and 24, Fagerstam et al. would have to teach each and every element thereof. It does not. Specifically, Fagerstam et al. does not teach a method of detecting antibodies in a blood or blood derivative solution comprising contacting the blood or blood derivative solution with a ganglioside-coated surface of a sensor chip.

The Examiner stated that claims 1, 4, 9, 10, 11, 12, and 24 are rejected under 35 U.S.C. §102(b) as being anticipated by Catimel et al. The Examiner stated that Catimel et al. (*Glycobiology*, vol. 8(9), 1998, pp.927-938) discloses an immobilization technique to investigate interactions between immobilized gangliosides (GD3, GM1, and GM2) and their respective antibodies, antibody fragments,

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or binding partners using an optical biosensor. The Examiner stated that immobilization was performed by direct injection onto a carboxymethyldextran sensor chip and did not require derivitization of the sensor surface or the ganglioside. The Examiner also stated that the ganglioside appeared to bind to the sensor surface by hydrophobic interaction, leaving the carbohydrate epitope available for antibody binding (see page 927, left column). The Examiner further stated that the sensor chip is designed for surface plasmon resonance (page 928, left column), and that the surface of the sensor chip also has a control blank channel with appropriate controls (see page 929).

In response, applicants respectfully traverse the Examiner's rejection.

To anticipate the method of claims 1, 4, 9, 10, 11, 12, and 24, Catimel et al. would have to teach each and every element thereof. It does not. Specifically, Catimel et al. does not teach a method of detecting antibodies in a blood or blood derivative solution comprising contacting the blood or blood derivative solution with a ganglioside-coated surface of a sensor chip.

In view of the preceding remarks, applicants maintain that the rejected claims satisfy the provisions of 35 U.S.C. §102(b), and request that the Examiner reconsider and withdraw the rejection.

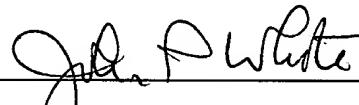
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee, apart for the \$55.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.



John P. White

Reg. No. 28,678

4/21/03

Date





Mark-Up Copy of the Amendments to the Claims

Claims 1, 9, 20, and 26 have been amended as follows:

1. (Amended) A method of detecting antibodies in a blood or blood derivative solution comprising:
 - a) contacting the blood or blood derivative solution with [an antigen] a ganglioside-coated surface of a sensor chip under conditions that permit [anti-[antigen]] the antibodies to bind to the [antigen] ganglioside coating;
 - b) detecting [the] a change in surface plasmon resonance signal of the sensor chip resulting from the [anti-antigen] antibodies binding to the [antigen] ganglioside coating.
4. The method of claim 1, [wherein the antigen is a ganglioside and] wherein the antibody is an anti-ganglioside antibody.
9. (Amended) The method of claim [8] 7, wherein the control antigen is Ganglioside GM2.
20. (Amended) The [A] method of claim 1, wherein [increasing] the [optical] surface plasmon resonance signal [size] is increased [of claim 1, comprising] by washing the [tested] solution from the surface of the sensor chip and applying a second solution containing [the] a secondary antibody to the surface.
26. (Amended) The method of claim [23] 27, wherein the disease is Guillain-Barré syndrome, motor neuropathy, peripheral neuropathy, or an autoimmune neuropathy.

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